REMARKS

Claims 1-39 are pending in the application. Claims 1 and 15, and the Abstract, have been amended. Support for the changes can be found throughout the Specification.

Supplemental Disclosure Statement

Upon review of the file, it was noted that the initialed Form PTO-1449 filed with the Supplemental Disclosure Statement dated April 1, 2003 has not been received. The same Supplemental Disclosure Statement was also noted in the last Office Action. It is respectfully requested that the Examiner initial the Form PTO-1449, a copy of which is enclosed for the Examiner's convenience, and return it to the undersigned attorney.

Examiner's Objection

The Examiner objected to the use of the word "said" in the Abstract of the Specification. Applicants have amended the Abstract to remove the word "said." Applicants respectfully request withdrawal of the objection.

Claim Rejections Under 35 U.S.C. § 112

In claims 1 and 15, The Examiner rejected to the term "generally" as rendering the claims indefinite under 35 U.S.C. § 112, second paragraph. Applicants have amended claim 1 and 15 to remove the term "generally." Applicants respectfully request withdrawal of the rejection.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1-39 are rejected under 35 U.S.C. § 103(a) as obvious over Garbe (USPN 5,688,523) in view of Scholz (USPN 6,019,997). The Examiner states that Garbe teaches an adhesive sheet material composed of "a water-soluble carrier comprising addition polymers (e.g. acrylates)," liquid excipients "which can read on plasticizers," and "a backing film." The Examiner acknowledges that Garbe does not teach an active agent, and relies on Scholz for that disclosure.

Applicants respectfully traverse the rejection. Garbe's "addition polymers" with the "liquid excipient" diffused in the polymer is equivalent in structure to Applicants'

adhesive layer. Garbe's "backing film" is equivalent in structure of the layers to Applicants' carrier layer. Garbe's optional release liners and differential release liners are equivalent in structure to Applicants' support layer or carrier layer.

As argued before, Applicants maintain that Garbe fails to teach that any layer is composed of water soluble/water dispersible material. In specifying the polymers for use in Garbe's disclosure, Garbe incorporates by reference the polymers listed in U.S. Patent No. 4,732,808 to Krampe (column 9, lines 50-57) and silicone polymers listed in U.S. Patent No. 5,232,702 to Pfister. The polymers listed in Krampe and Pfister are water-insoluble.

Even assuming for purposes of argument that Garbe taught water soluble polymers in the adhesive layer, which Applicants' dispute, Garbe fails to teach a water-soluble backing film. None of the conventional flexible backing materials listed in col. 3, lines 31-40 can be considered remotely water soluble. Further, Garbe makes no mention of including plasticizer in the backing film. Thus, even under the interpretation of Garbe put forth by the Examiner, Garbe would teach only one water-soluble layer (again which Applicants' dispute). In contrast, Applicants require that both layers, namely the adhesive layer and the carrier layer, be substantially water-soluble/water dispersible, as recited in independent claims 1 and 15.

Garbe, and the patents Garbe incorporates by reference, are concerned with transdermal delivery devices that provide pervasive adhesion on skin without excessive residue or adhesion loss (col. 1, lines 15-23; col. 5, lines 36-62). The patent does not teach or suggest a combination of layers, each layer capable of dissolving or dispersing once in contact with water. In contrast to the Office Action's characterization of the reference, Garbe lacks any discussion of water solubility at all. Rather, Garbe discusses the negative impact that strongly hydrogen bonding monomers affect compliance and require that the macromonomers of Krampe (which Applicants note are insoluble) are added to maintain compliance and increase the liquid excipient that can be loaded into the pressure sensitive adhesive. See col. 6, lines 2-25.

For at least these reasons, Garbe fails to disclose all the elements of the present invention to establish a *prima facie* case of obviousness.

Secondary Reference

Scholz fails to cure the deficiencies of Garbe. Scholz discloses a hydroalcoholic composition for transdermal delivery of a pharmaceutical agent. Scholz fails to teach or disclose a water soluble/water dispersible carrier layer or a water soluble/water dispersible adhesive layer, and only discloses use of the hydroalcoholic composition with transdermal delivery devices known in the art. Moreover, Garbe teaches that the polymers be soluble in the liquid excipients. There is no teaching or suggestion in Scholz that the hydroalcoholic compositions disclosed therein would be soluble in the polymers in Garbe for coating on a substrate. Thus, the combination of Garbe and Scholz fails to teach all elements of the present invention.

Garbe fails to disclose water-soluble polymer layers either alone or in combination with Scholz. Applicants request that the rejections under 35 U.S.C. § 103(a) should be withdrawn.

Conclusion

In view of the arguments offered herein, Applicants respectfully submit that the Examiner's grounds for objection and rejection are overcome and respectfully solicit reconsideration and withdrawal of the rejections to place the application in condition for allowance.

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Respectfully submitted,

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	Applicant(s): Kristen J. Godbey, Steven S. Kantner and Matthew T. Scholz	
	Filing Date: May 14, 2001	Gr up: 1615

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	SubClass	Filing Date If Appropriate
SH	✓	5,270,111	12/14/93	D'Haese et al.			

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	SubClass	Translation Yes	Translation No
SH	✓	1 110 546 A1	06/27/01	EPO	A61K	9/70	X	
SH	✓	WO 02/05789 A2	01/24/02	PCT	A61K	9/70		X

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

EXAMINER	Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.